

**U.S. NONPROVISIONAL PATENT APPLICATION**  
**UNDER 37 CFR § 1.53(b)**  
**FOR**  
**ELECTRICAL CONDUCTION BLOCK IMPLANT DEVICE**  
**BY**

**WILLIAM SWANSON; ST. PAUL, MN**

**RICHARD CORNELIUS; WAYZATA, MN**

**ROBERT S. SCHWARTZ; ROCHESTER, MN**

**INSKEEP INTELLECTUAL PROPERTY GROUP, INC.**  
1225 W. 190<sup>th</sup> Street, Suite 205  
Gardena, CA 90248

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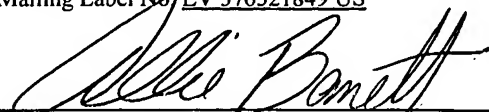
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## **ELECTRICAL CONDUCTION BLOCK IMPLANT DEVICE**

### **RELATED APPLICATIONS**

**[0001]** This application claims priority to U.S. Provisional Application Serial No. 60/451,865 filed March 3, 2003 entitled Implantable Device to Create Ostial Electrical Block in the Pulmonary Veins for Treatment of Atrial Fibrillation and to U.S. Provisional Application Serial No. 60/451,864 filed March 3, 2003 entitled Implantable Ring to Create Electrical Block in Pulmonary Vein Ostium for Treating Atrial Fibrillation, the entire contents of both being hereby incorporated by reference.

### **BACKGROUND OF THE INVENTION**

**[0002]** Pumping of the human heart is caused by precisely timed cycles of compartmental contractions of the heart muscle which lead to an efficient movement of blood into the heart and out to the various bodily organs. These precisely timed cycles are controlled and directed by electrical signals that are conducted through the cardiac tissue and can be referred to as pacing signals.

**[0003]** The sinoatrial node (SA node) is the heart's natural pacemaker, located in the upper wall of the right atrium. The SA node spontaneously contracts and generates nerve impulses that travel throughout the heart wall causing both the left and right atriums to sequentially contract according to a normal rhythm for pumping of the heart. These electrical impulses continue to the atrioventricular node (AV node) and down a group of specialized fibers called the His-Purkinje system to the ventricles. This electrical pathway must be exactly followed for proper functioning of the heart.

**[0004]** When the normal sequence of electrical impulses changes or is disrupted, the heart rhythm often becomes abnormal. This condition is generally referred to as an arrhythmia and can take the form of such arrhythmias as tachycardias (abnormally fast

heart rate), bradycardias (abnormally slow heart rate) and fibrillations (irregular heart beats).

**[0005]** Of these abnormal heart rhythms, fibrillations, and particularly atrial fibrillations, are gaining more and more attention by clinicians and health workers. Atrial fibrillation develops when a disturbance in the electrical signals causes the two upper atrial chambers of the heart to quiver instead of pump properly. When this happens, the heart is unable to discharge all of the blood from the heart's chambers thus creating a situation where the blood may begin to pool and even clot inside the atrium. Such clotting can be very serious insofar as the clot can break away from the atrial chamber and block an artery in the brain, and thereby cause a stroke in the individual.

**[0006]** A variety of treatments have been developed over the years to treat atrial fibrillation, namely, treatments to either mitigate or eliminate electrical conduction pathways that lead to the arrhythmia. Those treatments include medication, electrical stimulation, surgical procedures and ablation techniques. In this regard, typical pharmacological treatments have been previously disclosed in U.S. Pat. No. 4,673,563 to Berne et al.; U.S. Pat. No. 4,569,801 to Molloy et al.; and also by Hindricks, et al. in "Current Management of Arrhythmias" (1991), the contents of which are herein incorporated by reference.

**[0007]** Surgical procedures, such as the "maze procedure", have also been proposed as alternative treatment methods. The "maze" procedure attempts to relieve atrial arrhythmia by restoring effective atrial systole and sinus node control through a series of incisions.

**[0008]** The Maze procedure is an open heart surgical procedure in which incisions are made in both the left and right atrial walls which surround the pulmonary vein ostia and which leave a "maze-like" pathway between the sinoatrial node and the atrioventricular node. The incisions are sewn back together but result in a scar line which acts as a barrier to electrical conduction.

**[0009]** Although the "maze" procedure has its advantages, in practice it can be a complicated and a particularly risky procedure to perform since the surgeon is making

numerous physical incisions in the heart tissue. Due in part to the risky nature of the Maze procedure, alternative, catheter-based treatments have been advanced. Many of these catheter devices create the desired electrical block by way of ablation devices designed to burn lesions into the target tissue. Examples of these devices can be seen in U.S. patents: U.S. Pat. No. 6,254,599 to Lesh; U.S. Pat. No. 5,617,854 to Munsif; U.S. Pat. No. 4,898,591 to Jang et al.; U.S. Pat. No. 5,487,385 to Avitall; and U.S. Pat. No. 5,582,609 to Swanson, all incorporated herein by reference.

**[0010]** Although ablation catheter procedures remain less invasive than previous surgical methods like the “maze” procedure, they nevertheless retain a significant element of risk. For example, ablation procedures often utilize high power RF energy or ultrasonic energy, which may adequately create electrical block, but their inherent destructive nature allows for the possibility of unintended damage to the target tissue or nearby areas.

**[0011]** Further, it is often difficult to achieve certainty as to whether the appropriate amount of ablation has been performed uniformly around the perimeter of the target site or if the desired site is even being ablated.

**[0012]** Ablation procedures have also seen an occurrence of stenosis in the pulmonary veins as a response to the ablation. This is a serious complication and as a result, many doctors try to limit their treatment to the ostium of the pulmonary veins to minimize the risk of creating a stenosis in the pulmonary veins.

**[0013]** Finally, various implant devices have also been proposed. Examples of such proposed devices are disclosed in co-pending U.S. Application Serial Number 10/192,402 filed July 8, 2002 entitled Anti-Arrhythmia Devices and Methods of Use, the entire contents of which is hereby incorporated by reference.

**[0014]** The solutions in the prior art, however, are not believed to be entirely effective in many cases, and indeed may result in actually inducing long term arrhythmias and inefficacy.

**[0015]** As a result, what is needed are minimally invasive techniques for creating electrical block in the pulmonary veins which reduce the complication risk of previously known procedures, while increasing effectiveness and speed of the procedure to create electrical block.

## OBJECTS AND SUMMARY OF THE INVENTION

**[0016]** It is an object of the present invention to provide a minimally invasive device and technique for deploying such a device that safely and effectively blocks aberrant electrical signals at or near the ostium of the pulmonary veins.

**[0017]** It is a further object of the present invention to provide a minimally invasive electrical block device that is easy to deploy and has a low risk of complication.

**[0018]** It is yet a further object of the present invention to provide an electrical block device that consistently creates a circumferential scar line around the pulmonary ostium to completely block aberrant electrical signals causing atrial fibrillation.

**[0019]** The present invention achieves these objects by providing an electrical block implant sized and shaped for securement at the perimeter of the pulmonary ostium of the left atrium.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0020]** Figure 1A-1C illustrate three example variations of pulmonary ostia;

**[0021]** Figure 2 illustrates a flattened sectional view of an expandable ring according to the present invention;

**[0022]** Figure 3 illustrates a side view of an electrical block device according to the present invention;

**[0023]** Figure 4 illustrates the electrical block device of Figure 3 at a pulmonary vein bifurcation;

**[0024]** Figure 5 illustrates the electrical block device of Figure 3 in an expanded position;

**[0025]** Figure 6 illustrates the electrical block device of Figure 3 in a fully deployed position;

**[0026]** Figure 7 illustrates the electrical block device of Figure 3 in a fully deployed position;

**[0027]** Figure 8 illustrates a side view of an electrical block device according to the present invention;

**[0028]** Figure 9 illustrates a side view of an electrical block device according to the present invention;

**[0029]** Figure 10 illustrates a side view of an electrical block device according to the present invention;

**[0030]** Figure 11 illustrates a side view of an electrical block device according to the present invention;

**[0031]** Figure 11A illustrates a side view of an electrical block device according to the present invention;

**[0032]** Figure 12 illustrates a side view of an electrical block device according to the present invention;

**[0033]** Figure 13 illustrates a side view of an electrical block device according to the present invention;

**[0034]** Figure 14 illustrates a side view of an expandable ring according to the present invention;

**[0035]** Figure 15 illustrates a partial close up side view of an expandable ring according to the present invention;

**[0036]** Figure 16 illustrates a flattened sectional view of the expandable ring of Figure 14;

**[0037]** Figure 16A illustrates a cross-sectional view of a secondary ring of the device of Figure 14 as deployed at a target site in accordance with the present invention;

**[0038]** Figures 17A and 17B illustrate cross-sectional views of a conduction block device of the present invention in its implanted state;

**[0039]** Figure 18 illustrates another embodiment of the expandable ring design according to the present invention;

**[0040]** Figure 19 illustrates another embodiment of the expandable ring design according to the present invention;

**[0041]** Figure 20 illustrates a side view of an electrical block device according to the present invention;

**[0042]** Figure 21 illustrates a flattened sectional view of a primary expandable ring of Figure 20;

**[0043]** Figure 22 illustrates a top view of a secondary pressure ring according to the present invention;

**[0044]** Figure 23 illustrates a top view of a secondary pressure ring according to the present invention

**[0045]** Figure 24 illustrates a side view of an expandable ring according to the present invention;

**[0046]** Figure 24A illustrates a flattened sectional view of the expandable ring of Figure 24;

**[0047]** Figure 25 illustrates a side sectional view of an expandable ring according to the present invention;

**[0048]** Figure 26 illustrates a side sectional view of an expandable ring according to the present invention;

**[0049]** Figure 27 illustrates a flattened sectional view of the expandable ring of Figure 26;

**[0050]** Figures 28A-28C illustrate a preferred embodiment of a delivery system in accordance with the present invention;

**[0051]** Figures 29A-29C illustrate another preferred embodiment of a delivery system in accordance with the present invention;

**[0052]** Figure 30 illustrates another preferred embodiment of a delivery system in accordance with the present invention;

**[0053]** Figure 31 illustrates another preferred embodiment of a delivery system in accordance with the present invention;

**[0054]** Figure 32 illustrates another preferred embodiment of a delivery system in accordance with the present invention;

**[0055]** Figure 33 illustrates another preferred embodiment of a delivery system in accordance with the present invention;

**[0056]** Figure 34 illustrates a side view of an expandable ring according to the present invention;

**[0057]** Figure 35 illustrates a side view of an expandable ring according to the present invention;

**[0058]** Figure 36 illustrates a side view of a deployment apparatus according to the present invention;



**[0059]** Figure 37 illustrates a side perspective view of an electrical block device according to the present invention;

**[0060]** Figure 38 illustrates a side view of the electrical block device of Figure 35;

**[0061]** Figure 39 illustrates a magnified perspective view of the expandable ring of Figure 35;

**[0062]** Figure 40 illustrates a side view of the electrical block device of Figure 35 in a loaded state;

**[0063]** Figure 41 illustrates a side perspective view of the electrical block device of Figure 35;

**[0064]** Figure 42 illustrates a top view of the expandable ring of Figure 35 in an expanded state;

**[0065]** Figure 43 illustrates a top view of the expandable ring of Figure 42 in a cinched state;

**[0066]** Figure 44 illustrates a side perspective view of the electrical block device of Figure 35; and,

**[0067]** Figure 45 illustrates a top view of the electrical block device of Figure 35.

#### DETAILED DESCRIPTION OF THE INVENTION

**[0100]** The ostium of the pulmonary veins has a highly variable geometry from one patient to another and this presents difficulty in reliably treating atrial arrhythmias using previous methods. That is, the variable geometry has in the past made it difficult to reliably create a continuous line of electrical block around the perimeter of the ostium in each and every patient.

**[0101]** In illustration of this point, Figures 1A – 1C present three ostium geometries that can occur in the general human population. These Figures show a left atrium 10 of a human heart wherein two adjacent pulmonary veins 11 may originate directly from two ostia in the left atrium (Figure 1B) or may originate from one ostia in the left atrium followed by a bifurcation 13 downstream of the left atrium. Moreover, the bifurcation 13 may be located near the left atrium (Figure 1A) or far from the left atrium (Figure 1C). Finally, various hybrids of these geometries are also possible as some people can have more or less than the typical two pulmonary veins originating on each of the right and left sides of the left atrium 10.

**[0102]** In addition to these geometric variations, the ostia may differ in diameter and location of the side branches from patient to patient. For example, typical target site diameters may range anywhere from about 10 to 30 mm. This provides a considerable challenge for any consistently performed electrical block procedure for the treatment of an atrial arrhythmia.

**[0103]** To address this problem, the present invention provides an electrical block device that is implantable and anchorable within the pulmonary veins and/or left atrium of many different geometries. That is, the present invention presents a device and method that is adaptable for use in conducting substantially uniform treatment of a wide segment of the human population.

**[0104]** And generally speaking, the present invention performs this function in a way that consistently circumferentially blocks aberrant electrical signals through its presence in the ostium of the pulmonary veins. The electrical block device in accordance with the present invention may act through the mere presence in the ostium and/or through controlled scarring caused by the device.

**[0105]** The controlled scarring can be created by a number of possible mechanisms. One possible mechanism is to have the device press against the tissue with enough force to cause pressure necrosis. As the tissue necroses, the device slowly migrates through the wall and scar tissue forms behind the device as it slowly migrates through the tissue wall.

With this mechanism, it is possible that the device can ultimately migrate through the entire tissue wall leaving a line of scar through the entire wall thickness.

**[0106]** In another possible mechanism, the device can press against the tissue causing tension in the tissue wall. This tension in the tissue can cause fibrosis in the wall without having the device actually pass through the wall as was described for the pressure necrosis mechanism above.

**[0107]** Another possible mechanism is to have the presence of the device cause necrosis in the tissue as a result of a reaction to the material of the device or a material attached to the device. It is also possible to use combinations of these mechanisms.

**[0108]** The controlled scarring is believed to disrupt the cellular structure of cardiac tissue that is present in or on the pulmonary vein wall or the atrial wall outside the ostia and thereby prevent such cardiac tissue from propagating aberrant electrical signals that cause the atrial arrhythmias. While this invention describes use for electrical isolation of pulmonary veins, these same devices and methods can also be applied to other sites such as the superior vena cava or the coronary sinus.

**[0109]** Electrical Block Device With Anchoring Clip

**[0110]** A first preferred embodiment of the present invention is depicted in Figures 2–7 and comprises an electrical block device 100 that has three main functional components: an expandable ring 102, and an anchoring clip 106 and a clip loop 104 that connects the ring 102 with the clip 106.

**[0111]** With reference to Figures 6 and 7, it can be seen that in the fully deployed condition of the device 100 in an ostium 118 of a bifurcated pulmonary vein of the heart, the expandable ring 102 expands against the ostial tissue and the anchoring clip 106 abuts against the bifurcation 116 of the pulmonary veins 114. It can also be seen that the anchoring clip 106 is connected to the expandable ring 102 by the clip loop 104 that arcs over the diameter of the expandable ring 102.

**[0112]** The expandable ring 102 expands from its undeployed configuration by as much as 10 times or more beyond its size in a compressed state so as to press around the perimeter of the ostium. This expansile force assists in securing the expandable ring 102 in proper position.

**[0113]** In addition to its function of spatially positioning the device 100 in the ostial space, the expandable ring 102 also serves as the primary mechanism of creating the desired electrical conduction block. The expandable ring 102 can cause this electrical block either by inducing controlled scarring of the tissue contacted by the ring 102 or by the mere presence of the ring itself, or by a combination of the two. And as to the use of controlled scarring, any controlled method of scarring may be used, such as chemical coatings on the ring 102 that cause scarring, physical scarring devices mounted on the ring 102, or even mere physical expanding pressure from the ring 102 against the tissue.

**[0114]** Referring to Figure 2, the electrical block device 100 is shown in a cut and flattened sheet configuration for illustrative purposes. As is evident, the expandable ring 102 is structured from a continuous and regularly angled wire that forms an overall wave-like or sinusoidal shape. Two ends of the clip loop 104 extend from the expandable ring 102 portion of the device 100 and terminate in the wire structure that forms the anchoring clip 106.

**[0115]** Preferably, the wire that forms the electrical block device 100 is composed of nitinol or a similar elastic metal and is formed by heat setting to a fully expanded shape. Typically, this heat setting can be performed in an oven or salt bath, and yields a ring that is larger in its formed diameter than the target ostium diameter. As a result, the ring 102 exerts an outward force against the ostial wall when deployed, holding the device 100 in contact with the tissue.

**[0116]** The force exerted by the expandable ring 102 can be adjusted to a desired level by varying the thickness or width of the ring 102. The diameter/expansion ratio of the expandable ring 102 can also be varied to yield a different profile of force applied to the tissue upon expansion of the ring. Generally, increased expansion pressure better secures

the expandable ring 102 in place and may further create more prominent scarring at the target area.

**[0117]** In one preferred embodiment, the ring can be cut from a Nitinol tube having a diameter of about .150 inches and a wall thickness of about .015 inches. The struts of the ring can be cut about .015 inches wide and with a length between turnarounds of about .3 inches. For a target ostia having an internal diameter of 16mm, this ring could be cut with six cells (i.e., it could have six turnarounds on both the top and the bottom). For this 16mm target site, the ring could be formed to a diameter of about 20mm. It should be noted that these dimensions are merely exemplary and that these dimensions can vary.

**[0118]** As discussed above, the clip loop 104 arcs over the diameter of the expandable ring 102 when the device is deployed. As a result, as shown in Figures 6 and 7, the clip loop 104 serves to position the anchoring clip 106 at an appropriate distance from the expandable ring 102, and urge the anchoring clip 106 against the bifurcation 116 between the branches of the pulmonary vein. The curved design of clip loop 104 provides for some flexibility and "springiness" between the anchoring clip 106 and the expandable ring 102.

**[0119]** Referring to Figures 2 and 5, the anchoring clip 106 of the present preferred embodiment provides two closely spaced loops 103, having a single barb 105 within each of the loops 103. When a small portion of tissue of the bifurcation 116 moves between the two loops 103, the barbs 105 penetrate into the tissue and thereby retain the tissue between the two loops 103. Any type of clip or anchoring design may be used in place of the present anchoring clip 106 design, so long as the anchoring device can provide securing force from the expandable ring 102 to the tissue.

**[0120]** With regard to delivery of the electrical block device 100 to the target site, the electrical block device 100 is first compressed into an undeployed state and is placed within a deployment sheath 108, as seen in Figure 3. Within the deployment sheath 108 is a guiding catheter 112, used for positioning and deploying the electrical block device 100. The electrical block device 100 sits over the guiding catheter 112 such that the clip loop

104 is positioned between two guide wires 110 that extend out from the distal tip of the guiding catheter 112.

**[0121]** The guidewires 110 are conventional steerable guidewires having diameters typically in the range of .014 inches to .038 inches and must be steered down the two lumens past the bifurcation. Initially, the sheath 108 encapsulates the entire electrical block device 100 against the guiding catheter 112. However, as will be evident from the description below, this positioning configuration allows the electric block device 100 to easily slide off of the guiding catheter 112.

**[0122]** Referring to Figures 3 and 4, the loaded sheath 108 is advanced into the atrium, where the sheath is then partially retracted (or the guide catheter 112 is advanced out of the sheath 108) so that the clip loop 104 protrudes beyond the deployment sheath 108, thereby allowing the guide wires 110 to be more easily manipulated and positioned.

**[0123]** As the deployment sheath 108, guiding catheter 112, and electrical block device 100 are urged towards the pulmonary vein ostia, each guide wire 110 travels down a different pulmonary vein, centering the anchoring clip 106 on the bifurcation 116 of the pulmonary veins. The closer the guiding catheter 112 comes to the bifurcation 116, the more precisely aligned the anchoring clip 106 becomes with the bifurcation 116 until the anchoring clip 106 touches and finally “clips” onto the tissue of the bifurcation 116 via the barbs 105 located on the loops 103 of the clip 106.

**[0124]** The deployment process continues by simply sliding the deployment sheath 108 back past the expandable ring 102 as is best seen in Figure 5. Without the containment of the deployment sheath 108, the expandable ring 102 increases in diameter to its formed size, pressing on the target tissue.

**[0125]** With the electrical block device 100 secured, the guiding catheter 112 and deployment sheath 108 are backed out of the atrium and removed from the body, leaving the device 100 in its target location as seen in Figures 6 and 7.

**[0126]** Due to the variation in geometry of pulmonary ostia, a pre-operation procedure such as MRI may be helpful to determine the geometry and approximate diameter of the target ostium. With this information, the electrical block device 100 may be better adjusted to suit the patient's target ostium by adjusting aspects such as the expanded diameter of the expandable ring 102, the length of the clip loop 104, or the size of anchoring clip 106.

**[0127]** Electrical Block Device With Anchoring Barbs

**[0128]** The previously described preferred embodiment positioned and secured the anchoring clip 106 before securing the expandable ring 102. However, the reverse order is also possible according to a preferred embodiment shown in Figure 8.

**[0129]** The preferred embodiment as shown Figure 8 is generally similar to the previous embodiment, with perhaps two main exceptions. In the embodiment as shown in Figure 8, the first primary difference is the use of positioning barbs 220 with the expandable ring 220 and the second primary difference is the use of a clip loop 204 that is elastic.

**[0130]** The barbs 220 are located around the perimeter of expandable ring 202, providing additional anchoring support when the expandable ring 202 is in the fully expanded position. The elastic clip loop 204 secures on either side of the expandable ring 202, in the same manner as the previous embodiments. However, a portion of each side of the elastic clip loop 204 has a multi-angled, wave-like elastic section 205. This elastic section 205 allows for a degree of variation in the distance between the position of the deployed expandable ring 202 and the bifurcation 216.

**[0131]** In operation, the electrical block device 200 with anchoring barbs 200 is loaded and deployed in a manner similar to the previously described embodiment. The expandable ring 202 is loaded within a deployment sheath 208 and around a guiding catheter, with the elastic clip loop 204 to sit between guide wires 210.

**[0132]** The electrical block device 200 is positioned near the desired target tissue of the ostia and the guide wires 210 are inserted into each pulmonary vein 214. When a desired target location has been achieved, the deployment sheath 208 is withdrawn so as to

expose the expandable ring 202. The expandable ring 202 now being unconstrained, it expands and presses against the target tissue, pushing barbs 220 into the perimeter of the ostium 218.

**[0133]** Finally, the anchoring clip 206 is secured to the bifurcation 216 using guiding catheter 212 to apply pressure on the elastic clip loop 204 towards the bifurcation 216. This elastic section 205 enables the elastic clip loop 204 to stretch in response to the pressure and thus allows the anchoring clip 206 to secure to the bifurcation 216. At that point, the guiding catheter 212 and deployment sheath 208 may be removed from the patient.

**[0134]** In this manner, the electrical block device with anchoring barbs 200 provides the additional anchoring of barbs 220 while allowing for an alternative method of deployment. It should be understood that although this preferred embodiment allows the anchoring clip 206 to be clipped to the bifurcation 216 after expansion of the expandable ring 202, this order is not the only method of deployment. The electrical block device with anchoring barbs 200 may also be deployed in a similar fashion as electrical block device 100 of the first embodiment, as described above, where the anchoring clip 206 is clipped to the bifurcation 216 first, followed by deployment of the expandable ring 202.

**[0135]** Electrical Block Device Without Sheath

**[0136]** Figure 9 illustrates yet another preferred embodiment of the present invention. In this embodiment, the overall design of the electrical block device 300 is similar to the previously described embodiments; however, instead of utilizing a deployment sheath, a deployment wire 322 is used.

**[0137]** More specifically, as in previous embodiments, the electrical block device 300 is loaded on a guiding catheter 312 for desired positioning near the perimeter of the ostium. A clip loop 304 is positioned between two guide wires 310 at the tip of guiding catheter 312.

**[0138]** The main distinction of this design lies in the expandable ring 302, which, unlike previous embodiments, has a series of holes 320 integrated into the expandable ring 302



structure. As seen in Figure 9, a thin wire 322 passes through these holes 320 in a circular path and further passes through a catheter wire passage 324 within the guiding catheter 312, forming a large loop. The free ends of the thin wire 322 are found on the end opposite of the electrical block device 300 of the guiding catheter 312. Such a design allows the tension of wire 322 to control the expansion state of the expandable ring 302.

**[0139]** The overall operation of this electrical block device 300 is similar to the previously mentioned embodiments above. The user positions the guiding catheter 312 near the bifurcation 316 of the pulmonary veins, then attaches the anchoring clip 306 using the guide wires 310 to assist in proper positioning. Next, the user manipulates the thin wire 322 to relieve the compression of expandable ring 302, allowing the ring 302 to expand to its full diameter, pressing against the target tissue.

**[0140]** To remove the wire 322 from the electrical block device 300, a user simply pulls one end of the wire 322 until the opposite end is free of both the electrical block device 300 and the guiding catheter 312. At this point, the electrical block device 300 and the guiding catheter 312 are no longer connected, so the user may remove the guiding catheter from the patient, allowing the electrical block device 300 to function as intended.

**[0141]** This technique of controlling the deployment of the blocking device with a tether wire is shown here for a bifurcated ostium. It is anticipated that this same technique can be applied for other ostial geometries as will be described below.

**[0142]** Alternative Electrical Block Device Designs

**[0143]** It should be understood that variations on the above described electrical block devices are possible and even desired, depending on a number of factors such as the geometric layout of the ostium of the pulmonary veins. Five variations may be seen in the preferred embodiments of Figures 10 – 13. Consistent with the previous embodiments, these alternative embodiments similarly employ an anchoring structure and an expandable ring structure.

**[0144]** Referring to Figure 10, an electrical block device 400 is comprised of an expandable ring 402. Unlike previously described expandable rings, this expandable ring 402 has an overall warped structure, lending itself to placement analogous to a saddle over a bifurcation in a pulmonary ostium. In one variation, the expandable ring 402 includes anchoring barbs 403 to assist in securing the expandable ring 402 in place. In another embodiment (not shown), the anchoring barbs 403 may be absent and the expandable ring 402 is secured in place according to the expansion force of the ring 402 (based at least in part on the size and thickness of the ring 402) against the surrounding tissue.

**[0145]** In this embodiment, the expandable ring 402 has a wave-like structure similar to previously described embodiments, yet its overall conformation curves upward at the outer sides of the pulmonary veins while the inner portion warps downward toward the left atrium. This overall bent configuration allows the electrical block device 400 to wedge into place at the ostium of the pulmonary veins.

**[0146]** Referring to Figure 11, an electrical block device 404 is shown to have an expandable wire ring 408 and an expandable vein anchor 406. The wire ring 408 is an incomplete, non-continuous circle, formed to a diameter larger than the target pulmonary ostium which allows the wire ring 408 to self-expand against the target tissue.

**[0147]** The expandable vein anchor 406 has a circular wave-like (sinusoidal) structure which seats in a branch of the pulmonary vein just past the bifurcation and is connected to the expandable wire ring 408 with at least one wire. The vein anchor 406 has a similar structure to wave-like expandable rings described in previous embodiments. Functionally speaking, the vein anchor 406 expands in diameter against the pulmonary vein tissue providing additional anchoring force to secure the electrical block device 404 to the target position.

**[0148]** A variation of the embodiment in Figure 11 is shown in Figure 11A. This embodiment of an electrical conduction block device 700 uses a similar expandable wire ring 702 and an expandable vein anchor 704 connected by a connecting wire 706.

However, the expandable vein anchor 704 in this embodiment is helical as shown in Figure 11A.

**[0149]** Figure 12 illustrates yet another preferred embodiment of an electrical block device 410, this embodiment having an expandable ring 412 and dual ring anchors 414. As with previous embodiments, the expandable ring 412 is formed to have a diameter larger than the target ostium diameter, and is designed for seating close to the pulmonary ostium.

**[0150]** Each of the dual vein anchors 414 seats within a branch of the pulmonary vein, just past the bifurcation, and self expands to a diameter larger than the target diameter of the pulmonary vein and thereby is secured against the pulmonary vein tissue. Wire supports 411 connect the dual vein anchors 414 to the expandable ring 412 and thereby secure the electrical block device 410 in place.

**[0151]** Turning now to Figure 13, yet another preferred embodiment of an electrical block device 416 is illustrated. Although this embodiment also is usable with many ostial geometries, it is especially useful with pulmonary ostium having no bifurcation, as seen in Figure 13. Further, multiple electrical block devices 416 can be used for each patient, typically using one electrical block device for each pulmonary vein to provide complete electrical isolation between the left atrium and the pulmonary veins.

**[0152]** In this embodiment, the electrical block device 416 has an outer expandable ring 420 and an inner expandable ring 418. Both rings 420, 418 are secured together by wire support 422. The inner expandable ring 418 seats within a pulmonary vein, pressing outwardly against the vein tissue while the outer expandable ring 420 seats around the opening of the pulmonary vein. This embodiment allows the two rings to have either common or different functions. They can both be used to generate scarring as described above. They can also be configured such that the inner expandable ring 418 acts primarily as an anchoring/positioning ring and thereby allows outer expandable ring 420 to be held against the tissue around the ostium and to thereby serve as the scar generating ring.

**[0153]** Both rings 418, 420 have an angular wave-like design, allowing for compression in diameter during the pre-deployment phase and self-expansion during the deployment phase. In this fashion, electric block device 416 provides an alternative design for varying pulmonary geometries.

**[0154]** Electrical Block Device Coatings

**[0155]** The electrical block devices of the present invention as disclosed herein may be coated with a variety of chemicals or drugs to further enhance functionality. Such coatings may include drugs, chemicals, proteins, or other materials.

**[0156]** In one preferred embodiment of the present invention, portions of the electrical block device are coated with stenosis inhibiting drugs such as rapamycin or paclitaxel, as described in patents 6,273,913 and 6,231,600, the contents of which are hereby incorporated by reference.

**[0157]** The portions of the electrical block device which extend into the pulmonary vein may be of the most interest to coat, so as to limit the risk of pulmonary vein stenosis caused by the anchoring component of the implant yet not impacting the scarring response to the expandable ring desired in the ostium.

**[0158]** In another preferred embodiment, portions of the electrical block device are coated with a polymer material such as urethane or polyester, in order to promote the desired scarring around the ring while the anchoring components could remain uncoated or have a stenosis inhibiting coating as described above. Such a polymer coating could also be bio-absorbable, allowing for partial integration into the target tissue area.

**[0159]** In a further preferred embodiment, the expandable ring has a scar-inducing coating for enhancing the electrical blocking scar formation created by the expandable ring. Such coatings may include polymers, bioabsorbable polymers, platings (e.g., copper), polymers loaded with drugs (e.g., tetracycline), or drugs alone.

**[0160]** Expandable Ring Variations

**[0161]** Although the expandable electrical conduction block device of the present invention has been described in previous embodiments as primarily relying on a single zigzagging ring, it should be understood that a number of more complex variations are possible. Each variation may have different advantages beneficial to different pulmonary ostia geometries.

**[0162]** In a preferred embodiment seen in Figures 14-16, an expandable electrical conduction block device 500 is illustrated having a primary ring 504 (or primary "cell") and a secondary ring 502 (or secondary "cell"), formed from a single piece of material. As with previously described conduction block devices, this design may be compressed to a smaller size for loading into a deployment sheath or other deployment device so that it expands to a large diameter when free of such deployment devices. Figures 14 and 15 shows the conduction block device 500 in an expanded state while Figure 16 shows a sliced and flattened section of the device 500 in an unexpanded state.

**[0163]** The electrical conduction block device 500 has a primary ring 504 connected to a secondary ring 502 at the angled bend points or strut connection points of each ring. The primary ring 504 has a wider strut than the secondary ring 502, increasing the stiffness of the primary ring 504, while the secondary ring 502 is shorter in circumference than the primary ring 504. The differing circumferences of each ring allows for an expanded shape seen in Figure 14, with the secondary ring 502 fully extended to an essentially unbent circle and primary ring 504 extended to an overall wavy/sinusoidal shape. In a preferred embodiment, anchoring barbs 506 are present at the angled bend points of primary ring 504, providing additional anchoring force to maintain the target position of the electrical block device.

**[0164]** This two-ringed or two-cell design has a number of advantages, one of which is increased force per area on the target tissue by the secondary ring 502 relative to the primary ring 504. In this regard, the radial force exerted by the device against the wall of the target vessel is driven in large part by the width of the ring material. In other words, a wider ring can expand with more force than a thinner ring. A tissue necrosis mechanism for creating scars is a function of the pressure (force per unit area) exerted by the electrical

block device against the target tissue. Since the primary ring 504 is wider than the secondary ring 502 and the two rings are connected together (allowing some of the radial expansion force generated by the primary ring 504 to be applied to the tissue contacted by the secondary ring 502), the secondary ring 502 thus causes a greater amount of force per area as between the two. As a result, the secondary ring 502 can be designed to create a desired scar line while the primary ring 504 can be designed to provide the primary anchoring function.

**[0165]** In this regard, Figures 17A and 17B provide a cross-sectional view of how the secondary ring 502 causes the scarring response. Figure 17A shows the placement of the conduction block device 500 immediately after placement of the device 500 at the target site. As is evident, the barbs 506 have initially engaged the tissue wall but there is not yet any migration of the device into the tissue wall nor any scar line.

**[0166]** Figure 17B, on the other hand, shows the configuration of the conduction block device 500 after migration has occurred. As is evident in this embodiment, the greater force per area of the secondary ring 502 has caused the barbs 506 on the top end of the secondary ring 502 to extend into and even break through the tissue wall whereas the barbs 506 at the lower end of the primary ring 504 remain embedded in the tissue wall thickness. As is also evident, this migration has caused the creation of a scar line (indicated by the shaded area 503), including a scar line 503 that traverses the entire thickness of the tissue wall and encases or encapsulates the barb 506 of the secondary ring 502 that has extended through the tissue wall.

**[0167]** Another advantage to the dual ring design of the expandable ring 500 is that the secondary ring 502 is stretched into a nearly straight circle thereby allowing the secondary ring 502 to inscribe a substantially straight scar line around the internal circumference of the pulmonary vein. That is, the substantially straight scar line created by the secondary ring 502 avoids forming a scar line that extends axially upstream in the vein (away from the atrium) as would be the case if the secondary ring 502 was configured to have a wave-like shape in the deployed state.

**[0168]** This is important insofar as the electrical sources that must be isolated from the atrium in treating atrial arrhythmias are suspected to reside in close proximity to the ostium. These sources may be missed or inadequately isolated if the scar line, or a portion of the scar line, is created too far upstream in the vein (away from the atrium). Additionally, as discussed previously, the anatomy around the ostium often includes side branches or curves which make it more difficult to create a full circumferential scar line with a wave-like ring.

**[0169]** Finally, the electrical block device 500 that uses two rings (or “cells”) in this manner allows the formation of a discrete, narrow scar line yet has the positional stability of an axially extensive implant. In other words, the use of two rings 502, 504 in this manner leads to a narrow scar line around the ostium and also provides sufficient axial length so as to better ensure proper deployment and retention at the site. This is important as it is known that implants that have an increased ratio of diameter to axial length are more prone to misdeploy or “tumble” during deployment.

**[0170]** In a preferred embodiment of the expandable ring 500, the primary ring 504 and the secondary ring 502 are cut from a single tube of memory elastic metal, such as nitinol as shown in Figure 16. Each ring 502, 504 of the tubular structure is then stretched over a larger diameter ring and heat set in a furnace at about 540 degrees Celsius. The final formed diameter of each should allow the secondary ring 502 to stretch out to almost a straight circle as shown in Figures 14 and 15. The formed diameter of the expandable ring 500 is preferably larger in diameter than the target vessel by 5 – 100%, and more preferably by about 15% to 40%.

**[0171]** Electro-polishing components of the expandable ring 500 may be necessary to prevent micro surface cracks from propagating when the device is strained in forming. These cracks can cause the device to fracture and must be eliminated by polishing before applying high strain to the components. Nitinol components of the expandable ring 500 can be electro-polished using perchloric acid, nitric acid, or other compounds known to one skilled in the art. It may be desirable to form the device to a higher diameter in which case electro-polishing in stages may be necessary. This results from the fact that some

expansion may be needed before being able to polish uniformly and from the fact that polishing may need to precede final expansion.

**[0172]** Figures 18 and 19 show two possible other formed geometries for the conduction block device 500 described with reference to Figure 16. Figures 18 and 19 show the end of the device 500 with the secondary ring 502 being formed to a larger diameter than the end of the primary ring 504 without the secondary ring 502. As described earlier, the ratio of the diameter of the formed device to the diameter of the target site for the implant is an important driver of the magnitude of the radial force exerted by the device against the tissue of the target site. By forming the device tapered as in Figure 18 or flared as in Figure 19, it is possible to produce higher pressures against the tissue under the secondary ring 502 than under most if not all of the primary ring 504. This is independent of the pressure differences resulting from the width differences between the two rings as described previously. The result of this configuration is to have the secondary ring 502 apply enough pressure against the tissue wall to migrate through the wall due to pressure necrosis while most, if not all, of the primary ring 504 applies less pressure against the tissue so that it secures the position of the device 500 while creating reduced necrosis or fibrosis or, in some cases, perhaps no necrosis or fibrosis.

**[0173]** Referring to Figures 20-22, another embodiment of an electrical block device 511 is shown. As with the embodiment of Figures 14-16, this electrical block device 511 includes a primary ring 508 and a secondary ring 514. However, each ring 508, 514 is formed separately and later assembled to create the electrical block device 511 as discussed below.

**[0174]** The primary ring 508 has a wave shape in its expanded form as shown in Figure 20. It is formed from a tube with the cut path around the circumference of the tube shown in Figure 21. It includes barbed securing spikes 510 and anchoring spikes 512, as also is seen in Figure 18. These securing spikes 510 are sized to fit within spike apertures 515 that are disposed on the secondary ring 514 which is depicted in Figure 22. Thus, by inserting the barbed securing spikes 510 of the primary ring 508 into the spike apertures 515 of the secondary ring 514, the unitary electrical block device 511 is formed. The



assembled device 511 may then be compressed and expanded as needed for loading and deployment as discussed with previous embodiments. This embodiment allows the secondary ring 514 to project radially out further than the primary ring 508 as shown in Figure 20. This can aid in focusing the pressure against the tissue to the areas contacted by secondary ring 514.

**[0175]** Referring to Figure 23, an alternate preferred embodiment may comprise a secondary ring 516 that functions as described with previous embodiments but that further includes a plurality of points 519 arranged around its outer edge. These points provide additional anchoring force, as well as additional scarring capability for the secondary ring 516.

**[0176]** Referring to 24 and Figure 24A, another preferred embodiment of an electrical block device 535 is contemplated wherein the primary ring 536 has struts 537 that are longer than the struts of the primary ring of previous embodiments. Furthermore, the secondary ring 538 is attached to the primary ring 536 with connection strands 533 that extend from the bottom of the secondary ring 538 to the bottom of the struts 537 of the primary ring. This differs from previously described embodiments wherein the secondary ring 538 is connected to the top of the struts of the primary ring 536. As a result, a higher percentage of the main expansion force generated by the primary ring 536 is delivered through the secondary ring 538. It also leads to the primary ring 536 extending axially beyond the secondary ring 538 whereas in previous embodiments, the primary ring is essentially below the secondary ring.

**[0177]** An advantage to this configuration is as follows. The larger surface area provided by the primary ring 536 leads to a greater dispersion of the expansion pressure (force per unit area) against the tissue by the primary ring 536 and thus mitigates (or even eliminates) the tendency of the struts of the primary ring 536 to penetrate or migrate through the wall of the vessel tissue. At a minimum, this greater surface will slow down the migration rate of the struts as compared to other embodiments and as to the struts of the secondary ring 538. It does not, however, negatively affect the desired expansion pressure (force per unit area) of the secondary ring 538. Hence, a first advantage is that the primary ring 536 may

better facilitate the anchoring properties of the device 535 without degrading the scar inducing properties of the secondary ring 538.

**[0178]** Another advantage of this configuration relates to how the scar inducing properties of the device are executed by the device 535. If the struts 537 of the primary ring 536 are prevented from migrating into the wall of the tissue, this will better ensure the proper migration of the struts of the secondary ring 538. For example, if the struts of one side of the secondary ring 538 migrate fully through the wall on one side of the vessel before similar migration by the struts on the other side of the secondary ring 538, the circumferential tension (caused by the vessel tissue) necessary for urging the oppositely sided struts to continue their migration will be released unless an independent force is exerted against these oppositely sided struts. This independent force is provided by the struts 537 of the primary ring 536 as follows. Since the struts 537 of the primary ring 536 have not migrated into the tissue (by virtue of the larger surface area of these struts), they retain their expansion force. And because these struts 537 are independently connected to the struts of the secondary ring 538, then the oppositely sided struts of the secondary ring 538 will continue to encounter the outward expansion forces of the primary ring 536. As a result, uniform migration of the struts of the secondary ring 538 into the surrounding tissue is substantially assured even if the migration of the entire circumference of the secondary ring 538 does not occur simultaneously. In other words, by having the primary ring 536 serve essentially only as an anchoring ring (by virtue of its increased area), uniform outward expansion force is exerted against the struts of the secondary ring 538, regardless of when a portion of the secondary ring may migrate through the vessel tissue.

**[0179]** Referring to Figure 25, a variation of the embodiment of Figures 24 and 24A may include an electrical block device 520 wherein the struts 525 of the primary ring 522 not only extend beyond the struts of the secondary ring 524 but the struts 525 are configured to flare outwardly beyond the normal diameter of the device 520. Configuring the struts 525 in this manner allow the electrical block device 520 to better conform to the structure of the ostium and pulmonary vein since typically the ostium expands outwardly as it merges with

the atrial wall. This configuration may cause the primary ring 522 to have even better anchoring properties than the embodiment of Figures 24 and 24A.

**[0180]** Referring to Figures 26 and 27, another preferred embodiment for causing tissue scarring with an expandable ring is an electrical conduction block device 530 that includes a series of small barbs 532 along the length of each strut 531 of the device 530. These barbs 532 serve to pierce the tissue wall of the vessel at the same time that the device 530 is being expanded against the vessel wall. The barbs 532 create small cuts along the pressure path and thereby reduce the pressure (force per unit area) needed for each strut 531 to migrate through the vessel wall.

**[0181]** The barbs can be cut in the pattern shown in the flat sheet depiction of the device 530 in Figure 27, wherein the barbs 532 lay flat, i.e., they lay circumferentially on the device instead of radially outwardly. The barbs 532 can then be bent into a radially outward position when the device is formed up to its final diameter. Typically this occurs automatically if the ratio of strut thickness to strut width is decreased below about 1.0.

**[0182]** Furthermore, the embodiment depicted in Figures 26 and 27 can be used alone, i.e., as the sole component of the electrical conduction block device or it can be used in a two-ring or "two-cell" design as discussed previously. Referring to Figure 27, the device 530 can serve as a primary ring as in previously described embodiments wherein a secondary ring can be connected via the apertures that are located at one end of the struts 531 of the device 530.

**[0183]** It is desirable to deploy the device in a very controlled and accurate way for all embodiments of the electrical block devices discussed in accordance with the present invention. This includes the capability of deploying the device with a smooth release from the delivery device with no "jumping" of the position of the device in the target vessel. It also includes the capability of repositioning the device or to remove the device if the physician is not pleased with the deployed position of the device.

**[0184]** One embodiment of such a delivery system useful particularly for the electrical block devices described previously with respect to Figures 13-27 is shown in Figures 28A-28C. Figure 28A shows an electrical block device 500 having a primary 504 and secondary ring 502 being deployed out of the end of the delivery catheter 700 into the ostium of a pulmonary vein. This deployment is initiated by drawing back the external sheath 702 to allow the block device 500 to expand up towards its formed diameter.

**[0185]** Figure 28B shows the electrical block device 500 now fully expanded at the site in the ostium of the pulmonary vein ostium. In this drawing it can be seen that the electrical block device 500 is attached to the delivery catheter 700 by an array of arms 539 projecting out from a hub 704 on the inner shaft 705 of the delivery catheter 700. These arms 539 are connected to the secondary ring 502 of the electrical block device 500. This array of arms 539 connected to the electrical block device 500 allows the deployment of the device 500 to be controlled according to the rate the outer sheath 702 is pulled back. In the partially deployed state shown in Figure 28A, the sheath 702 constrains the expansion of the arms 539 which then act to hold down the electrical block device 500.

**[0186]** This type of an assembly allows the device 500 to be deployed gradually by controlling the rate that the sheath 702 is pulled back along the catheter. This assembly also allows recovery or repositioning of the electrical block device 500 if the physician so wishes by advancing the sheath 702 back over the arms 539 and the electrical block device 500. Figure 28C shows the delivery catheter 700 being withdrawn away from the deployed electrical block device 500 after releasing the connection of the arms 539 from the device 500.

**[0187]** Figures 29A-29C show a variation on delivery catheter design described above. In this embodiment the loops formed by the secondary ring 502 of the fully constrained electrical block device 500 shown in Figure 16 are used to connect the electrical block device 500 to the delivery catheter 700. These loops are hooked over a ring of pins 540 and are thereby trapped inside the sheath 702 of the delivery catheter 700 until the sheath 702 is withdrawn back beyond the ring of pins 540. Figure 29B shows how this allows the primary ring 504 to be deployed while retaining connection to the secondary ring 502 inside

the end of the sheath 702. If satisfied with the location of the primary ring 504, the sheath 702 is then withdrawn fully releasing the secondary ring 502 as shown in Figure 29C.

**[0188]** Figure 30 shows one embodiment in which the arms 539 are hollow tubes having a wire 708 running from the handle of the catheter 700, down the shaft of the catheter to the array of arms 539, then inside the arm and out the end. This wire 708 is then wrapped around the strut of ring 502 and back into the arm 539. This wire 708 runs back down the arm to a releasable anchor point (not shown) in the catheter 700 shaft or back in the handle (not shown). This connects the arm 539 to the strut 502. After the electrical block device 500 has been deployed, the device 500 can be released by releasing the anchor point on the wire 708 and pulling the wire 708 out from the catheter handle as is shown in the far right view of Figure 30.

**[0189]** Figure 31 shows another embodiment of a connecting mechanism in accordance with the invention. In this embodiment, the strut of the secondary ring 502 has a notch 710 which provides a nest for a mating notched end of the arm 539. Arm 539 has a wire 708 running along it from the catheter handle like that described with respect to Figure 30. This wire 708 runs through holes 712 in the arm 539 on either side of the strut 502 forming a loop around the strut. The mating notches between the strut 502 and the arm 539 act to absorb any axial load that may occur between these two elements during delivery. The connection may be released after deployment of the electrical block device 500 by pulling the wire 708 back through the holes 712 from the catheter handle as shown in right views of Figure 31.

**[0190]** Figure 32 shows another embodiment of a connecting mechanism in accordance with the present invention. In this embodiment, the strut of the secondary ring 502 has a small hole 714 cut in it. The end of the arm 539 has a "U" shaped cradle 716 with holes 718 cut in each side of the cradle 716. The strut is placed in this "U" shaped cradle 716 during assembly and a small pull wire 708 as described previously relative to Figures 30 and 32 is threaded through the holes 718 in the "U" shaped cradle 716 and the strut 502. After deployment of the electrical block device 500, this connection can be released by pulling this wire 708 back through these holes 714, 718 as shown in the right views of Figure 32.

**[0191]** Figure 33 shows another embodiment of a connecting mechanism in accordance with the present invention. In this embodiment, the strut of the secondary ring 502 has a small hole 720. This hole 720 has a pair of wires 722, 724 strung through it. One of these wires 722 has an increased diameter 726 on its end that will fit through the hole 720 when it is the only wire passing through the hole 720 but will not fit back through the hole 720 if the second wire 724 has been passed through the hole 720 after the increased diameter end 726 of the first wire 722 has passed through the hole 720. In this way, the second wire 722 acts as a pin to "lock" the first wire 724 through the hole 720. This process can be reversed as shown in Figure 33 by withdrawing the second wire 724 and then withdrawing the first wire 722 through the hole 720.

**[0192]** As mentioned earlier, the concepts disclosed relative to the previously discussed connecting mechanisms could also be used to attach a delivery device to the electrical block device 500 at locations other than the strut of the secondary ring 502 as shown above. For example, a connecting mechanism such as is shown in Figure 33 could also be well suited to a hole geometry such as that shown in Figure 9. In this case the pairs of wires 722, 724 would extend radially out from the shaft of the catheter 700 to pass through the holes in the blocking device. These wires could be radially extended or drawn back with a handle connected to these wire pairs. In this way the wires could be used to control the radial expansion of the electrical block device 500 as was described earlier, and be released from the electrical block device 500 when desired by withdrawing the second wire and then the first wire as shown in Figure 33.

**[0193]** Variably Expandable Electrical Block Device

**[0194]** Yet another preferred embodiment of the present invention illustrates a variably expandable electrical block device 600 and deployment apparatus 616, illustrated in Figures 34-45. Generally, this device 600 functions in a manner similar to previously described embodiments by causing scarring at the ostium of the pulmonary veins. However, the structure of the variably expandable electrical block device varies from previous designs in that it utilizes a non-continuous expandable ring 602 that allows for compact loading and deployment.

**[0195]** Figure 34 shows the non-continuous expandable ring 602 in its flattened, loaded position, while Figure 35 shows the ring 602 in its natural coiled position. The expandable ring 602 has two notable elements: anchoring barbs 604 and ring wire holes 606. As the name implies, anchoring barbs 604 provide anchoring support by penetrating the target tissue when the expandable ring 602 is in its natural coiled position. This anchoring support prevents the expandable ring 602 from migration away from the target area while securing portions of the expandable ring 602 to the ostium. Ring wire holes 606 are simply holes within expandable ring 602 that allow a control wire 618 to pass through.

**[0196]** Referring to Figure 36, the deployment device 616 is shown to have a deployment sheath 614 and a deployment catheter 612. The deployment catheter 612 is an elongated instrument that slides within deployment sheath 614. Located on the end of deployment catheter 612 are control arms 608, preferably made from nitinol, which serve to deploy the expandable ring 602 at a target location as discussed in greater detail below. Control arm wire holes 610 can be seen at the ends of each control arm 608, allowing for control wires 618 to pass through each of the holes 610 and into a center channel (not shown) of the deployment catheter 612.

**[0197]** Referring to Figures 37 and 38, the present preferred embodiment uses two control wires 618 for manipulating the expandable ring 602. Each control wire 618 takes an overall looped path, extending out of and through the center channel in deployment catheter 612, through a control arm wire hole 610, into ring wire hole 606, across the diameter of the deployed expandable ring 602, then through the opposite side's ring wire hole 606, into an opposite control arm wire hole 610, and finally into the center channel in deployment catheter 612. Each control wire 618 consequently crosses the diameter of expandable ring 602 such that that when both control wires 618 are present, an "X" pattern spans the diameter of the expandable ring 602.

**[0198]** A user may tighten or loosen these two control wires 618 to manipulate the size of the expandable ring 602. Figures 42 and 43 best illustrate this function, as the expandable ring 602 is shown in an expanded and contracted position, respectively.

**[0199]** The control wires 618 also serve the secondary function of deflecting the anchoring barbs 604 inward to prevent the sharp tips from being exposed until the control wire 618 is withdrawn. This deflection can be best seen in Figure 39.

**[0200]** Referring to Figure 40, the variably expanding electrical block device 600 can be seen in a loaded state within the deployment sheath. As with previous embodiments of the present invention, the expandable ring 602 remains within the deployment sheath 614 until the end of the deployment sheath reaches the target location of the pulmonary ostium. Note that control wires 618 are not shown for simplicity of illustration.

**[0201]** One of the inherent benefits of this design lies in its ability to pass through significantly smaller diameter deployment sheaths for delivery to the desired target site, while expanding to an appropriate diameter, similar to the previously disclosed embodiments of this application.

**[0202]** Preferably, the expandable ring 602 could be cut from a flat sheet or tubing made from nitinol, having a thickness of about .015 inches and a height of about .070 inches. However, a variety of thicknesses and heights may be used so long as loading into a deployment sheath is possible and proper expansion of the expandable ring 602 may be achieved.

**[0203]** This embodiment of the present invention may be operated by first finding the pulmonary ostium target area with the loaded deployment apparatus 616 as depicted in Figure 40. Referring to Figures 40 and 37, the user pushes deployment catheter 612 within the deployment sheath 614, which, in turn, pushes expandable ring 602 out from the deployment sheath 614. The user continues pushing the deployment catheter until control arms 608 are fully extended from the deployment sheath. During this movement, the expandable ring 602 curls back on itself from its straight shape, forming its relaxed, circular ring shape. This results in the system having the configuration depicted in Figure 37 in the left atrium.



**[0204]** Referring to Figures 41, 42 and 43, the user is able to control the diameter of expandable ring 602 for purposes of matching the ring with the target site by simply pulling on the control wires 618 to decrease the diameter and/or releasing the wires to increase the diameter. Typically, a user will pull the control wires 618 to decrease the expandable ring 602 diameter so as to allow the user to then easily position the ring 602 at the target position of the ostium.

**[0205]** In this regard, the control arms 608 are devised so as to have sufficient axial strength so that the user may use them to push the expandable ring 602 forward. The user can track along a guide wire until either the expandable ring 602 wedges into the ostium or until the ring 602 is aligned with a predetermined axial marker of the desired deployment position.

**[0206]** Referring to Figures 44 and 45, once the proper target position is achieved, the user releases the control wires 618 which then allow the expandable ring 602 to increase in diameter, pushing against the target tissue. When the user is satisfied that the expandable ring 602 is in the proper position, the final step of deployment is performed, namely separating the deployment apparatus 616 from the expandable ring 602. To do this, a user must first remove control wires 618 from the expandable ring 602 by pulling on one end of each control wire 618. Since only one end of the control wire 618 is being pulled, the opposite end will be pulled through its path in the expandable ring 602 and out of the control end of the deployment catheter 612. Each control wire 618 is pulled out of the electrical block device 600 in a similar manner.

**[0207]** When all of control wires 618 are pulled out, the anchoring barbs 604 are free to bend outwardly from the expandable ring 602 and penetrate the target tissue. Additionally, the deployment apparatus 616 is free to be retracted and removed from the patient, and the procedure may be finished, as best seen in Figure 44 and 45.

**[0208]** Optionally, additional anchoring devices may be used to help secure the electrical block device. Typically, such devices include staples or sutures which are not integral parts

of the ring but which are delivered with a separate device that can be tracked into position and fasten the expandable ring to the tissue wall.

**[0209]** Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.